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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/574,688 | 04/05/2006 | Takumi Takeyasu | Q94159 | 3724 |
| 23373 | 7590 | 01/16/2008 | EXAMINER | |
| SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 | | | HAVLIN, ROBERT H | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,688

Applicant(s)

TAKEYASU ET AL.

Examiner

Robert Havlin

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 7-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 7-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims: Claims 1-3, and 7-57 are currently pending. Claims 53-57 were newly presented. Claims 1, 9, 18, 24, 37, and 45 were amended. Claims 4-6 were cancelled.

Declarations: The 37 CFR 1.132 declaration was considered.

Claim Rejections

In response to applicant's arguments in bullet 1: the term synthon is defined in March's Advanced Organic Chemistry as "a structural unit within a molecule that can be formed and/or assembled by known conceivable synthetic operations." Thus, the examiner's prior characterization of a synthon as a "synthetic equivalent" is correct. The language of claim 1 was amended to incorporate the term synthon.

35 USC 112 2nd rejection

Claims 1-3, 7, 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of the phrase "synthon of formaldehyde" in claim 1 does not have a definite meaning that would allow one of ordinary skill in the art to recognize the metes and bounds of the claim. As defined above, the term synthon does not have a definite meaning, but instead refers to a conceptualization of a structural unit formed by any known conceivable synthetic operation. Thus, by definition, the term synthon is indefinite without a full description of all of the *currently known* conceivable synthetic operations able to generate the structural unit. Although the claim includes the language "at least one selected from the group consisting of ..."

this does not further define the synthon, but instead gives a few exemplary species while allowing for inclusion of other unknown entities. Furthermore, the term synthon of formaldehyde is not concisely defined in the specification and only has exemplary references relating to the terminology.

35 USC 102(b) rejections

The rejection of claims 1-3, 7-14, and 32-44 under 35 USC 102(b) is hereby withdrawn as a result of applicant's amendment of the claims to incorporate the structural limitation in claim 1 of "wherein the indole derivative in reaction step 1 is not substituted at the 3-position."

35 USC 103(a) rejection

Regarding newly presented claims 53-57, these claims are also rejected under 35 USC 103(a) as being obvious over Shiota in view of Katritzky. For the reasons given in the prior office action the newly presented claims drawn to dialkylaminomethyl-substituted are also obvious. Applicant claims that Katritzky merely discloses an intermediate and does not provide any motivation to one of ordinary skill in the art to use it with Shiota to arrive at the claimed invention. This argument is not found persuasive because Katritzky is within the contemplation of one of ordinary skill in the art for use with Shiota because it teaches methods of making indole derivatives which is exactly what the instant application is attempting to do.

Regarding claims 15 and 15, the 103(a) rejection is maintained because one of ordinary skill in the art would immediately recognize that protecting group chemistry is appropriate when forming a peptide bond regardless of applicant's out-of-context

citation of Schelhaas stating that no protect group is desirable. Schelhaas teaches the optimal choice of protecting groups in complex multistep synthesis involving the formation of a peptide bond, which is exactly what this application is attempting to perform.

In addition, contrary to applicant's statements on page 31 of the response, the prior office action does not assert anything regarding which combinations of solvents is "better." However, as stated in the prior rejection of claim 16, the claims are using well known methods in peptide chemistry and therefore remains obvious.

Regarding applicant's arguments at #3 on page 31, the examiner pointed to potential motivations for modifying the synthetic scheme taught by Shiota to start with simpler, readily available starting materials. This reasoning still holds true. In addition, one of ordinary skill in the art of organic synthesis is motivated to optimize yields of reactions to obtain the most product possible in a single reaction. Routine methods of achieving this goal include reformulating reactions using well known synthetic routes to arrive at the desired product. Therefore, the modifications claimed in this application are akin to routine optimizations of the teachings of Shiota and is therefore obvious.

Again, applicant's arguments at #4 that one of ordinary skill in the art would not know to use well known protecting group chemistry methods as taught by Schellhass is not persuasive. Furthermore, use of a palladium catalyst for removing protecting groups as disclosed in Schellhass is well known in the art and one of ordinary skill in the art would know to apply it in this situation.

In conclusion to the addressing of applicant's arguments against the obviousness of the claims, the examiner maintains that claims 1-3 and 7-57 are obvious over the prior art and are properly rejected under 35 USC 103(a).

The rejection of claims 4, 5, 18, and 19 under 35 USC 112, 1st paragraph is maintained. The applicant has only listed three possible options of what a synthon of formaldehyde is. In addition, example 15 of the specification is the only working example where a synthon of formaldehyde, namely formalin (which is formaldehyde in water), was used. Given that the application has listed only three possibilities and given only one working example, one of ordinary skill in the art would not recognize that the applicants actually possessed the claimed invention.

Claim Objections

The claims were amended to sufficiently address the claim objections of the prior office action.

Conclusion

No claims are in condition for allowance. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
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Art Unit 1626

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